AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in this application. The following amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed. Applicants reserve the right to pursue the subject matter of the canceled claims in this or any other appropriate patent application.

Listing of the Claims:

1. - 52. **(Cancelled)**

53. **(Currently amended)** The method of claim 63, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise a pancreatic enzyme.

54. **(Previously presented)** The method of claim 63 or 78, wherein the normal fecal chymotrypsin level is a level of fecal chymotrypsin associated with at least one other individual of the same approximate age that does not have the disorder.

55. **(Currently amended)** The method of claim 63 or 78 wherein the normal fecal chymotrypsin level is about ~~8.4 U/gm~~8.4 U/gram.

56. **(Cancelled).**

57. **(Previously presented)** The method of claim 63 or 78 wherein the pharmaceutical composition is administered three to six times per day.

58. **(Previously presented)** The method of claim 63 or 78, further comprising determining the individual's fecal chymotrypsin level after administration of the pharmaceutical composition.

59. **(Previously presented)** The method of claim 63 or 78, wherein an overall CARS score from the CARS test for the individual decreases after administration of the pharmaceutical composition as compared to an overall CARS score from the CARS test for the individual prior to administration of the pharmaceutical composition.

60. (**Previously presented**) The method of claim 63 or 78, wherein the individual exhibits an improvement after administration of the pharmaceutical composition in one or more of the CARS test individual components selected from: visual response; verbal body skills, touch/taste/smell; object use; emotion; intellect; relating; listening; imitation; body use; adaptation to change; activity level; and general impression.

61. (**Previously presented**) The method of claim 63 or 78, wherein the individual exhibits an amelioration in an autistic symptom after administration of the pharmaceutical composition wherein said amelioration in an autistic symptom is increased eye contact; increased toilet training; increased speech; formed bowel movements; reduced hyperactivity; increased play with others; or reduced hand flapping.

62. (**Cancelled**).

63. (**Currently amended**) A method for treating autism in an individual comprising:

administering a CARS (childhood autism rating scale) test to the individual prior to administration of a pharmaceutical composition comprising ~~one or more~~ digestive enzymes comprising a lipase, an amylase and a protease to determine the degree in which autism symptoms are present;

determining if the individual has a fecal chymotrypsin level less than normal;

administering the pharmaceutical composition comprising digestive enzymes comprising a lipase, an amylase and a protease to the individual if the fecal chymotrypsin level is less than normal; and

administering a CARS test to the individual after administration of the pharmaceutical composition to determine the degree in which autism symptoms are present post-administration~~, wherein the individual has a self-limiting diet consisting primarily of carbohydrates~~.

64- 65. (**Cancelled**).

66. **(Currently amended)** The method of claim 63 or 78, wherein the individual's fecal chymotrypsin level is below ~~8.4 U/gm~~8.4 U/gram.

67. **(Currently amended)** The method of claim 63 or 78, wherein the individual's fecal chymotrypsin level is below ~~8.4 U/gm~~8.4 U/gram but above or equal to ~~4.2 U/gm~~4.2 U/gram.

68. **(Currently amended)** The method of claim 63 or 78, wherein the individual's fecal chymotrypsin level is below ~~4.2 U/gm~~4.2 U/gram.

69. **(Previously presented)** The method of claim 63 or 78, wherein the individual's fecal chymotrypsin level is determined using an enzymatic spectrophotometry method.

70-71. **(Cancelled)**.

72. **(Currently amended)** The method of claim 63, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise amylase, protease, lipase, sucrase, cellulase, and maltase enzymes.

73. **(Currently amended)** The method of claim 63, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise chymotrypsin and trypsin enzymes.

74 - 77. **(Cancelled)**.

78. **(Previously presented)** A method for treating autism in an individual comprising:

administering a CARS (childhood autism rating scale) test to the individual prior to administration of a pharmaceutical composition to determine the degree in which autism symptoms are present;

determining if the individual has a fecal chymotrypsin level less than normal;

administering the pharmaceutical composition to the individual if the fecal chymotrypsin level is less than normal; and

administering a CARS test to the individual after administration of the pharmaceutical composition to determine the degree in which autism symptoms are present post-administration, wherein the pharmaceutical composition comprises digestive enzymes, wherein the digestive enzymes comprise proteases, from 4000 to 20,000 USP of lipases per dose, and from 10,000-60,000 USP of amylases per dose.

79. (**Currently amended**) The method of claim 63, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise pancreatin from 2000 to 6000 USP per dose.

80. (**Previously presented**) The method of claim 78, wherein the proteases comprise 2-5 mg of chymotrypsin per dose and 60-100 mg of trypsin per dose.

81 - 82. (**Cancelled**).

83. (**Currently amended**) The method of claim 91, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise a pancreatic enzyme.

84. (**Previously presented**) The method of claim 91 or 106, wherein the normal fecal chymotrypsin level is a level of fecal chymotrypsin associated with at least one other individual of the same approximate age that does not have the disorder.

85. (**Currently amended**) The method of claim 91 or 106, wherein the normal fecal chymotrypsin level is about ~~8.4 U/gm~~8.4 U/gram.

86 - 88. (**Cancelled**).

89. (**Previously presented**) The method of claim 91 or 106, wherein the individual exhibits an amelioration in an autistic symptom after administration of the pharmaceutical composition wherein said amelioration in an autistic symptom is increased eye contact; increased toilet training; increased speech; formed bowel movements; reduced hyperactivity; increased play with others; or reduced hand flapping.

90. (**Cancelled**).

91. (**Currently amended**) A method for treating autism in an individual comprising:

evaluating one or more autistic symptoms in the individual prior to administration of a pharmaceutical composition comprising ~~one or more~~ digestive enzymes comprising a lipase, an amylase and a protease;

determining if the individual has a fecal chymotrypsin level less than normal;

administering a pharmaceutical composition comprising ~~one or more~~ digestive enzymes comprising a lipase, an amylase and a protease to the individual if the fecal chymotrypsin level is less than normal,

evaluating one or more autistic symptoms in the individual prior to administration of a the pharmaceutical composition~~, wherein the individual has a self-limiting diet consisting primarily of carbohydrates~~.

92. **(Cancelled).**

93. **(Currently amended)** The method of claim 91 or 106, wherein the individual's fecal chymotrypsin level is below ~~8.4 U/gm~~8.4 U/gram.

94. **(Currently amended)** The method of claim 91 or 106, wherein the individual's fecal chymotrypsin level is below ~~8.4 U/gm~~8.4 U/gram but above or equal to ~~4.2 U/gm~~4.2 U/gram.

95. **(Currently amended)** The method of claim 91 or 106, wherein the individual's fecal chymotrypsin level is below ~~4.2 U/gm~~4.2 U/gram.

96. **(Canceled)**

97. **(Previously presented)** The method of claim 91 or 106, wherein the individual's fecal chymotrypsin level is determined using an enzymatic spectrophotometry method.

98. **(Previously presented)** The method of claim 97, wherein the enzymatic spectrophotometry method is performed at 30 °C.

99. **(Cancelled)**

100. (**Currently amended**) The method of claim 91, wherein the ~~one or more~~ digestive enzymes comprise amylase, protease, lipase, sucrase, cellulase, and maltase enzymes.

101. (**Currently amended**) The method of claim 91 or 106, wherein the ~~one or more~~ digestive enzymes comprise ~~comprises~~ chymotrypsin or trypsin enzymes.

102 - 105. (**Cancelled**)

106. (**Previously presented**) A method for treating autism in an individual comprising:

evaluating one or more autistic symptoms in the individual prior to administration of a pharmaceutical composition;

determining if the individual has a fecal chymotrypsin level less than the normal fecal chymotrypsin level;

administering the pharmaceutical composition to the individual if the fecal chymotrypsin level is less than the normal fecal chymotrypsin level,

evaluating one or more autistic symptoms in the individual after administration of the pharmaceutical composition, wherein the pharmaceutical composition comprises digestive enzymes, wherein the digestive enzymes comprise proteases, from 4000 to 20,000 USP of lipases per dose, and from 10,000-60,000 USP amylases per dose.

107. (**Currently amended**) The method of claim 91, wherein the ~~one or more~~ digestive enzymes comprise ~~comprises~~ ~~comprises~~ pancreatin from 2000 to 6000 USP per dose.

108. (**Currently amended**) The method of claim 106, wherein the digestive enzymes ~~comprises~~ comprise 2-5 mg of chymotrypsin per dose or 60-100 mg of trypsin per dose.

109. (**Cancelled**)

110. **(Currently amended)** The method of claim 118, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise a pancreatic enzyme.

111. **(Previously presented)** The method of claim 118 or 132, wherein the normal fecal chymotrypsin level is a level of fecal chymotrypsin associated with at least one other individual of the same approximate age that does not have the disorder.

112. **(Currently amended)** The method of claim 118 or 132, wherein the normal fecal chymotrypsin level is about ~~8.4 U/gm~~8.4 U/gram.

113 - 115. **(Cancelled)**

116. **(Previously presented)** The method of claim 118 or 132, wherein the individual exhibits an amelioration in an autistic symptom after administration of the pharmaceutical composition wherein said amelioration in an autistic symptom is increased eye contact; increased toilet training; increased speech; formed bowel movements; reduced hyperactivity; increased play with others; or reduced hand flapping.

117. **(Previously presented)** The method of claim 118 or 132, wherein the individual has a history of gastrointestinal (GI) dysfunction.

118. **(Currently amended)** A method for treating autism in an individual comprising:

administering one or more diagnostic tests to determine the severity of one or more autistic symptoms in the individual prior to administration of a pharmaceutical composition comprising ~~one or more~~ digestive enzymes comprising a lipase, an amylase and a protease;

determining if the individual has a fecal chymotrypsin level less than normal;

administering a pharmaceutical composition comprising ~~one or more~~ digestive enzymes comprising a lipase, an amylase and a protease to the individual if the fecal chymotrypsin level is less than normal;

administering one or more diagnostic tests to determine the severity of the one or more autistic symptoms in the individual after administration of the pharmaceutical composition~~, wherein the individual has a self-limiting diet consisting primarily of carbohydrates~~.

119. (**Cancelled**)

120. (**Currently amended**) The method of claim 118 or 132, wherein the individual's fecal chymotrypsin level is below ~~8.4 U/gm~~8.4 U/gram.

121. (**Currently amended**) The method of claim 118 or 132, wherein the individual's fecal chymotrypsin level is below ~~8.4 U/gm~~8.4 U/gram but above or equal to ~~4.2 U/gm~~4.2 U/gram.

122. (**Currently amended**) The method of claim 118 or 132, wherein the individual's fecal chymotrypsin level is below ~~4.2 U/gm~~4.2 U/gram.

123. (**Previously presented**) The method of claim 118 or 132, wherein the individual's fecal chymotrypsin level is determined using an enzymatic spectrophotometry method.

124. (**Previously presented**) The method of claim 123, wherein the enzymatic spectrophotometry method is performed at 30 °C.

125. (**Cancelled**)

126. (**Currently amended**) The method of claim 118 or 132, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise amylase, protease, lipase, sucrase, cellulase, and maltase enzymes.

127. (**Currently amended**) The method of claim 118 or 132, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise chymotrypsin or trypsin enzymes.

128 - 131. (**Cancelled**).

132. **(Previously presented)** A method for treating autism in an individual comprising:

administering one or more diagnostic tests to determine the severity of one or more autistic symptoms in the individual prior to administration of a pharmaceutical composition;

determining if the individual has a fecal chymotrypsin level less than normal;

administering a pharmaceutical composition to the individual if the fecal chymotrypsin level is less than normal;

administering one or more diagnostic tests to determine the severity of the one or more autistic symptoms in the individual after administration of the pharmaceutical composition, wherein the pharmaceutical composition comprises digestive enzymes, wherein the digestive enzymes comprise proteases, from 4000 to 20,000 USP of lipases per dose, and from 10,000-60,000 USP amylases per dose.

133. **(Currently amended)** The method of claim 118, wherein the digestive enzymes ~~comprises~~ comprise pancreatin from 2000 to 6000 USP per dose.

134. **(Currently amended)** The method of claim 132, wherein the proteases comprise ~~comprises~~ 2-5 mg of chymotrypsin per dose or 60-100 mg of trypsin per dose.

135. **(Cancelled)**

136. **(Previously presented)** The method of claim 155 or 169, wherein a diagnosis of autism in the autistic individual is confirmed prior to administration of the pharmaceutical composition.

137. **(Previously presented)** The method of claim 155 or 169, wherein prior to administration of the pharmaceutical composition, one or more diagnostic tests to determine the severity of one or more autistic symptoms in the autistic individual are performed.

138. (**Previously presented**) The method of claim 155 or 169, wherein after administration of the pharmaceutical composition, one or more diagnostic tests to determine a reduction in the severity of one or more autistic symptoms in the autistic individual are performed.

139. (**Previously presented**) The method of claim 155 or 169, wherein prior to administration of the pharmaceutical composition, the fecal chymotrypsin level of the autistic individual is determined.

140. (**Previously presented**) The method of claim 139, wherein the fecal chymotrypsin level is compared to a normal fecal chymotrypsin value.

141. (**Previously presented**) The method of claim 140, wherein the fecal chymotrypsin level is below normal.

142-144. (**Cancelled**)

145. (**Currently amended**) The method of claim 155, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise pancreatic enzymes.

146. (**Currently amended**) The method of claim 155, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise pancreatin.

147. (**Currently amended**) The method of claim 155, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise one or more of a cellulase, a sucrase, and a maltase.

148. (**Previously presented**) The method of claim 140, wherein the normal fecal chymotrypsin level is a level of fecal chymotrypsin associated with at least one other individual of the same approximate age that does not have the autism disorder.

149. (**Currently amended**) The method of claim 140, wherein the normal fecal chymotrypsin level is about ~~8.4 U/gm~~8.4 U/gram.

150 - 151. (**Cancelled**)

152. (**Previously presented**) The method of claim 139, further comprising determining the autistic individual's fecal chymotrypsin level after administration of the pharmaceutical composition.

153. (**Previously presented**) The method of claim 155 or 169, wherein the autistic individual exhibits an amelioration in an autistic symptom after administration of the pharmaceutical composition wherein said amelioration in an autistic symptom is increased eye contact; increased toilet training; increased speech; formed bowel movements; reduced hyperactivity; increased play with others; or reduced hand flapping.

154. (**Previously presented**) The method of claim 155 or 169, wherein the autistic individual has a history of gastrointestinal (GI) dysfunction.

155. (**Currently amended**) A method of treating autism in an autistic individual comprising administering a pharmaceutical composition comprising ~~one or more~~ digestive enzymes comprising a lipase, an amylase and a protease to the autistic individual, wherein the individual has a fecal chymotrypsin level less than normal~~, wherein the autistic individual has a self-limiting diet consisting primarily of carbohydrates~~.

156. (**Cancelled**)

157. (**Currently amended**) The method of claim 139, wherein the autistic individual's fecal chymotrypsin level is below ~~8.4 U/gm~~8.4 U/gram.

158. (**Currently amended**) The method of claim 139, wherein the autistic individual's fecal chymotrypsin level is below ~~8.4 U/gm~~8.4 U/gram but above or equal to ~~4.2 U/gm~~4.2 U/gram.

159. (**Currently amended**) The method of claim 139, wherein the individual's fecal chymotrypsin level is below ~~4.2 U/gm~~4.2 U/gram.

160. (**Previously presented**) The method of claim 139, wherein the individual's fecal chymotrypsin level is determined using an enzymatic spectrophotometry method.

161-162. **(Cancelled)**

163. **(Currently amended)** The method of claim 155 or 169, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise amylase, protease, lipase, sucrase, cellulase, and maltase enzymes.

164. **(Currently amended)** The method of claim 155 or 169 wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise chymotrypsin and trypsin enzymes.

165 - 168. **(Cancelled)**

169. **(Currently amended)** A method of treating autism in an autistic individual comprising administering a pharmaceutical composition to the autistic individual, wherein the pharmaceutical composition comprises digestive enzymes, wherein the digestive enzymes comprise proteases, from 4000 to 20,000 USP of lipases per dose, and from 10,000-60,000 USP amylases per dose, wherein the individual has a fecal chymotrypsin level less than normal.

170. **(Currently amended)** The method of claim 155, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise pancreatin from 2000 to 6000 USP per dose.

171. **(Previously presented)** The method of claim 169, wherein the proteases comprise 2-5 mg of chymotrypsin per dose or 60-100 mg of trypsin per dose.

172. **(Currently amended)** The method of claims 63, 91, 118, or 155, wherein the ~~one or more~~ digestive enzymes ~~comprises~~ comprise an amylase, protease, lipase, sucrase, cellulase or maltase.

173. **(Cancelled)**

174. **(Currently amended)** The method of claim 172~~173~~, wherein the protease is trypsin or chymotrypsin.

175. **(Previously presented)** The method of claims 78, 106, 132, or 169, wherein the proteases comprise from 10,000 to 50,000 USP.

176. **(Previously presented)** The method of claim 175, wherein the proteases further comprise 2-5 mg of chymotrypsin per dose or 60-100 mg of trypsin per dose.